CLAIMS

1. Multilayer pharmaceutical form for controlled active ingredient release, comprising

a) optionally a neutral core (nonpareilles),

b) an inner controlling layer comprising a substance having a modulating effect, which is embedded in a matrix which influences the delivery of the modulatory substance and which comprises pharmaceutically usable polymers, waxes, resins and/or proteins, and where appropriate an active ingredient,

c) an active ingredient layer comprising an active pharmaceutical ingredient and, where appropriate, a substance having a modulating effect,

d) an outer controlling layer comprising at least 60% by weight of one or a mixture of a plurality of (meth)acrylate copolymers composed of 98 to 85 C_1 to C_4 alkyl esters of (meth)acrylic acid and 2 to 15% by weight of methacrylate monomers with a quaternary ammonium group in the alkyl radical, and, where appropriate, up to 40% by weight of further pharmaceutically usable polymers,

where the layers may additionally and in a manner known per se comprise pharmaceutically usual excipients.

2. Multilayer pharmaceutical form according to Claim 1, characterized in that the matrix of the inner controlling layer comprises one or more of the following polymers:

copolymers of methyl methacrylate and/or ethyl acrylate and methacrylic acid, copolymers of methyl methacrylate, methyl acrylate and methacrylic acid, copolymers of methyl methacrylate, butyl methacrylate and dimethylethyl methacrylate, copolymers of methyl methacrylate, ethyl acrylate and trimethylammoniumethyl

methacrylate, copolymers of methyl methacrylate and ethyl acrylate, copolymers of ethyl acrylate, methyl acrylate, butyl methacrylate and methacrylic acid,

polyvinylpyrolidones (PVPs), polyvinyl alcohols, polyvinyl alcohol-polyethylene glycol graft copolymer (Kollicoat®), starch and derivatives thereof, polyvinyl acetate phthalate (PVAP, Coateric®), polyvinyl acetate (PVAc, Kollicoat), vinyl acetate/vinylpyrolidone copolymer (Kollidon® VA64), vinyl acetate: crotonic acid 9:1 copolymer (VAC: CRA, Kollicoat® VAC), polyethylene glycols with a molecular weight above 1000 (g/mol), chitosan, a (meth)acrylate copolymer consisting of 20-40% by weight of methyl methacrylate and 60 to 80% by weight of methacrylic acid, a crosslinked and/or uncrosslinked polyacrylic acid, an Na alginate, and/or a pectin,

celluloses such as, for example, anionic carboxymethylcellulose and salts thereof (CMC, Na-CMC, Ca-CMC, Blanose, Tylopur), carboxymethylethylcellulose (CMEC, Duodcell®), hydroxyethylcellulose (HEC, Klucel), hydroxypropylcellulose (HPC), hydroxypropylmethylcellulose (HPMC, Pharmacoat, Methocel, Sepifilm, Viscontran, Opadry), hydroxymethylethylcellulose (HEMC), ethylcellulose (EC, Ethocel®, Aquacoat®, Surelease®), methylcellulose (MC, Viscontran, Tylopur, Methocel), cellulose esters, cellulose glycolate, cellulose acetate phthalate (CAP, Cellulosi acetas, PhEur, cellulose acetate phthalate, NF, Aquateric®), cellulose acetate succinate (CAS), cellulose acetate trimeliate (CAT), hydroxypropylmethylcellulose phthalate (HPMCP, HP50, HP55), hydroxypropylmethylcellulose acetate succinate (HPMCAS-LF, -MF, -HF).

3. Multilayer pharmaceutical form according to Claim 1, characterized in that the matrix of the <u>inner controlling layer</u> comprises a wax such as, for example, carnauba wax and/or beeswax.

4. Multilayer pharmaceutical form according to Claim 1, characterized in that the matrix of the inner controlling layer comprises the resin shellac.

5. Multilayer pharmaceutical form according to Claim 1, characterized in that the matrix of the inner controlling layer comprises a protein such as, for example, albumin, gelatin, zein, collagen, gluten and/or a lectin.

6. Multilayer pharmaceutical form according to one or more of Claims 1 to 5, characterized in that the substance having a modulating effect has a molecular weight below 500 and is in solid form and is ionogenic.

7. Multilayer pharmaceutical form according to Claim 6, characterized in that substance having a modulating effect is soluble in water.

8. Multilayer pharmaceutical form according to Claim 6 or 7, characterized in that the substance having a modulating effect is an organic acid or the salt of an organic or inorganic acid.

9. Multilayer pharmaceutical form according to one or more of Claims 1 to 8, characterized in that the substance having a modulating effect is succinic acid, citric acid, tartaric acid, laurylsulphuric acid, a salt of these acids or a salt of the following anions: taurochlolate and other cholates, chlorides, acetates, lactates, phosphates and/or sulphates.

10. Process for producing a multilayer pharmaceutical form according to one or more of Claims 1 to 9 in a manner known per se by means of spraying processes or fluidized bed granulation.